MAY 17 2002

510(k) SUMMARY
Collins Medical Infant Plethysmograph
K011344

Date: Revised May 14, 2002

1. **Submitter:** Collins Medical, Inc.
220 Wood Road
Braintree, MA 02184

2. **Contact Person:**
Donald Henton
Quality System / Regulatory Affairs Manager

Telephone: 781-843-0610

3. **Device Name:**
Proprietary Name: IPL (Infant Pulmonary Laboratory) or Collins infant Plethysmograph
Classification Name: Plethysmograph, Pressure

4. **Predicate Devices:**
Collin Body Plethysmograph Plus System
Collins Pneumotach PFT System
EBS 2605 Infant Hugger
Sensormedics Model 2600 Pediatric Pulmonary Cart
PEDS PUFF

5. **Intended Use**: To perform plethysmography and spirometry, including the use of large mandatory breaths and forced exhalation (hugger) in pediatric populations. For use in infants from 17 weeks post full term birth to pediatric populations up to 36" in length to perform pulmonary function assessment including raised lung V_{30} measurements.

6. **Description:** This is a consolidated version of Collins' Small and Large Infant Plethysmograph (preamendment) devices, Body Plethysmograph Plus System and Pneumotach PFT System. It includes the Infant Hugger bladder and jacket as a standard feature, IBM compatible computer running Windows®, and it incorporates diagnostic software changes combined into a comprehensive system for measuring fractional lung volumes (FLV), single breath or passive exhalation technique measures compliance (C) and resistance (R) of the respiratory system, and maximal expiratory flow-volume curves (MEFVC), via plethysmography and spirometry. A test protocol developed through a Cystic Fibrosis Therapeutics Development Network and National Institute Health (NIH) sponsored grant has been incorporated to standardize the Infant Pulmonary Function Testing (IPFT). It is also based on the work of Andre Feher, et al, Flow limitation in normal infants: a new method for forced expiratory maneuvers from raised lung volumes, J Appl. Physiology,

80(6): 2019-2025, 1996, and Robert Castile, et al, Adult-Type Pulmonary Function Tests in Infants Without Respiratory Disease, Pediatr Pulmonol. 30: 215-227, 2000.

8. **Technological Characteristics**:

The IPL or Infant Plethysmograph model 004400 uses the same kind of acrylic enclosure construction as the earlier Baby Plethysmograph models, but has added an angle cut that now allows easier access to the face and head area of the child, and the lower part slides on a track to fully expose the Plethysmograph bed when open. The box is capable of measuring pressure changes of 0 to 5 psid with an accuracy of +/- 2% FSO, and the pneumotach measures from 0 - 160 L/min with an accuracy of +/- 2%.

9. Conformity to Recognized Standards:

Electrical safety: UL 2601-1, IEC 601-1-1, and CSA 22.2 No. 1
Emissions and Immunity: IEC 601-1-2
Performance: *Standards for infant respiratory function testing: Plethysmographic measurements of lung volume and airway resistance.* European Respiratory Society 2000

Respiratory Mechanics in Infants: Physiologic Evaluation in Health and Disease. American Thoracic Society / European Respiratory Society 1993

10. **Conclusion**: Test results have demonstrated that the Infant Plethysmograph is substantially equivalent in safety and effectiveness to the former marketed predicate devices with respect to its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 17 2002

Collins Medical, Inc.
c/o Mr. Jonathan S. Kahan
Hogan and Hartson L.L.P.
555 Thirteenth Street NW
Washington, DC 20004-1109

Re: K011344
Infant Plethysmograph Model 004400
Regulation Number: 868.1750 / 868.1840 / 868.1880
Regulation Name: Plethysmograph, Pressure / Spirometer, Diagnostic / Calculator, Pulmonary Function Data
Regulatory Class: II (two)
Product Code: 73 CCM / BZG / BZC
Dated: February 25, 2002
Received: February 25, 2002

Dear Mr. Kahan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 1

510(k) Number (if known): K011344

Device Name: IPL (Infant Pulmonary Laboratory) or Infant Plethysmograph

Indications For Use: To perform plethysmography and spirometry, including the use of large mandatory breaths and forced exhalation (hugger) in pediatric populations. For use in infants from 17 weeks post full term birth to pediatric populations up to 36" in length to perform pulmonary function assessment including raised lung V_{30} measurements.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓

Division of Cardiovascular & Respiratory Devices
510(k) Number K011344

(optional Format 3-10-98)